

### **Remarks**

Following entry of the above amendment, claim 19 is newly added. Support for newly added claim 19 is found in the specification as filed on page 6, lines 38-42. Claims 9-12 and 15-18 were previously canceled. Claims 1-8, 13-14 and 19 remain pending.

#### **I. Obviousness-type double patenting rejection**

Claims 1-8, 13 and 14 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7,084,139 ('139). For at least the reasons cited in Section II below, applicants assert that the pending claims are separately patentable over claims 1-10 of the '139 patent.

#### **II. Claim rejections under 35 U.S.C § 102**

##### **A. The '139 patent fails to make any crystalline forms of the claimed compound.**

Claims 1-8, 13 and 14 were rejected under 35 U.S.C. §102 as allegedly inherently anticipated by U.S. Patent No. 7,084,139 ('139). Applicants respectfully traverse this rejection. "Anticipation requires the presence in a single prior art reference disclosure of every element of the claimed invention." *Great Northern Corp. v. Davis Core & Pad. Co., Inc.*, 228 U.S.P.Q. 356, 358 (Fed. Cir. 1986). Because the presently claimed crystalline form is not present in the '129 patent, there can be no anticipation.

Applicants wish to point out that in the specification of the present application on page 2, lines 21-24, it is stated that, "(E)-2-(5-Chlorothien-2-yl)-N-[(3S)-1-[(1S)-1-methyl-2-morpholin-4-yl-2-oxoethyl]-2-oxopyrrolidin-3-yl]ethanesulfonamide is a FXa inhibitor disclosed in WO02/100886 and WO02/100830, incorporated herein by reference, in a substantially amorphous form". Emphasis Added. WO02/100886 is the PCT Published application equivalent of the '139 patent.

Simply put, the '139 patent fails to describe any crystalline form whatsoever of (E)-2-(5-Chlorothien-2-yl)-N-[(3S)-1-[(1S)-1-methyl-2-morpholin-4-yl-2-oxoethyl]-2-oxopyrrolidin-3-yl]ethanesulfonamide. Instead, the '139 patent describes in column 153, Example 386 the synthesis of (E)-2-(5-Chlorothien-2-yl)-N-[(3S)-1-[(1S)-1-methyl-2-morpholin-4-yl-2-oxoethyl]-2-oxopyrrolidin-3-yl]ethanesulfonamide in two routes, one of which forms an amorphous solid, and

the other, a clear oil. Neither of these exemplified preparations of the compound result in a crystalline form.

Route 1 describes the synthesis of solid (E)-2-(5-Chlorothien-2-yl)-N-[(3S)-1-[(1S)-1-methyl-2-morpholin-4-yl-2-oxoethyl]-2-oxopyrrolidin-3-yl]ethenesulfonamide from starting intermediates followed by a wash in sodium bicarbonate, water and brine. The resulting washed organic layer is then dried over magnesium sulphate and concentrated under reduced pressure to give the title compound as a white solid. Applicants assert that one of skill in the art would readily recognize that the resulting white solid of route 1 is an amorphous form of the claimed compound and not a crystalline compound.

Route 2, on the other hand, results in the title compound being formed as a clear oil. Again, one of skill in the art would understand that a clear oil is not the same as the crystalline compound of claim 1.

For at least these reasons, applicants assert that the '139 patent fails to describe or even suggest the crystalline form of the compound in claim 1 of the present application. The Examiner is therefore invited to point out on the record where, if at all, the '139 patent shows the synthesis of a substantially crystalline form of (E)-2-(5-Chlorothien-2-yl)-N-[(3S)-1-[(1S)-1-methyl-2-morpholin-4-yl-2-oxoethyl]-2-oxopyrrolidin-3-yl]ethenesulfonamide.

**B. The '139 patent teaches solvated forms of compounds, but not substantially crystalline compounds.**

The office action of April 16, 2008 stated that the '139 patent teaches using organic solvents to crystallize the material in column 24. This is not correct. Instead, the '139 patent teaches using organic solvents to form solvates, not crystalline forms. Applicants respectfully submit that column 24 recites solvated forms of the compounds embraced by the '139 patent. In particular, column 24, lines 64-67 through column 25, lines 1-3 states, "...many organic compounds can form *complexes* with *solvents* in which they are reacted or from which they are precipitated or crystallized. These complexes are known as *solvates*..." *Emphasis added* Applicants respectfully submit that the pending claims are patentably distinct from '139; and therefore, request favorable reconsideration of this rejection under 35 U.S.C. §102(a).

Applicants believe the present claims are in condition for allowance and such action is respectfully requested. If the Examiner has any outstanding issues with the pending claims, he is encouraged to telephone the undersigned at (919) 483-8406 for expeditious handling.

Respectfully submitted,



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